

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION**

MARK A. BARRY, MD,

Plaintiff,

v.

MEDTRONIC, INC.,

Defendant.

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Civil Action No. 1:14-104-RC

Judge Ron Clark

**MEDTRONIC, INC.'S MOTION FOR JUDGMENT AS A MATTER OF LAW
AT THE CLOSE OF PLAINTIFF'S CASE**

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Medtronic Inc. (“Medtronic”) files this motion for judgment as a matter of law under Federal Rule of Civil Procedure 50(a) at the close of plaintiff’s case.

ARGUMENT

I. No Reasonable Jury Could Find Induced Infringement Under § 271(b)

As a threshold matter, Dr. Barry must prove direct infringement by third parties to support a finding of inducement. *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2117 (2014). But no reasonable factfinder could conclude that surgeons directly infringe the asserted claims of the ’358 patent or the ’121 patent. Dr. Barry has failed to prove any instances of direct infringement of either patent.

Direct Infringement of the ’358 patent- Dr. Barry has failed to establish that surgeons perform all steps of the asserted method claims of the ’358 patent. There is no evidence that Medtronic’s accused VCM Kit contains “pedicle screw engagement members which are mechanically linked with ... handle means” as required by the asserted claims. *See* PX 1 at 6:15-17 (Claim 1). There is also no evidence that surgeons select a second pedicle screw cluster derotation tool, also required by the asserted claims. *Id.* at 7:60-63.

Direct Infringement of the ’121 patent- Dr. Barry has failed to establish direct infringement of the asserted system claims in the ’121 patent. As with the ’358 patent, there is no evidence that the accused VCM Kit includes two pedicle screw cluster derotation tools, each of which has “pedicle screw engagement members which are mechanically linked with [a] handle means.” PX 2 at 8:5-7 (Claim 2). Dr. Barry has also failed to show: (a) that the VCM kit has a “group of three or more pedicle screw engagement members” that are mechanically linked with handle means; (b) that the VCM kit includes the “pedicle screw engagement member[s]”

that each must be linked to its own handle means (i.e. “said first handle means having a handle linked to each pedicle screw engagement member of the first group of three or more pedicle screw engagement members”); and (c) that the VCM kit includes instruments whereby the handles on each side of the spine must be linked together by “a linking member.” *See id.* at 8:5-45.

The asserted claims of both patents require both a “first handle means” and “second handle means.” Dr. Yassir testified, however, that a single handle means could be both the “first” and “second” handle means for purposes of infringement. *See, e.g.*, Day 3 Tr. 821:13-16; Day 4 Tr. 962:20-963:3, 964:19-24, 967:1-4; 1026:14-1027:1. This is plainly contrary to law. *Becton, Dickinson and Co. v. Tyco Healthcare Grp, LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010) (“Where a claim lists elements separately, ‘the clear implication of the claim language’ is that those elements are ‘distinct component[s]’ of the patented invention.” (quoting *Gaus v. Conair Corp.*, 363 F.3d 1284, 1288 (Fed. Cir. 2004))); *see also Regents of Univ. of Minn. v. AGA Med. Corp.*, 17 F.3d 929, 934-939 (Fed. Cir. 2013) (affirming that claim reciting “first and second occluding disks” required separate disks); *3M Innovative Prop. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1371 (Fed. Cir. 2003) (affirming the district court’s claim construction that “first . . . pattern” and “second . . . pattern” refer to different patterns and equating them to “pattern A” and “pattern B”). Dr. Yassir’s testimony that a single handle means could satisfy this limitation was contrary to law and is, therefore, not evidence of infringement.

Further, the survey relied upon by Dr. Neal and Dr. Yassir as evidence of direct infringement is wholly unreliable. Medtronic renews its motion that the survey should have been excluded under *Daubert*. *See* Dkt. 208; *Procter & Gamble Pharm., Inc. v. Hoffmann-LaRoche Inc.*, 2006 WL 2588002, at *21-27 (S.D.N.Y. Sept. 6, 2006) (rejecting consumer and physician

surveys for failure to apply the “generally accepted survey principles” laid out in the Reference Manual on Scientific Evidence). Specifically, the survey failed to include all claim limitations—for example, it failed to ask the respondents whether they used any “handle means,” let alone the *two* separate handle means required by each asserted claim; whether the derotators were “mechanically linked” to “handle means”; and whether the surgical procedure achieved an “amelioration of aberrant spinal column deviation conditions.” *See generally* PX 1, PX 2; *see also Seal-Flex, Inc. v. Athletic Track & Court Const.*, 172 F.3d 836, 842 (Fed. Cir. 1999) (plaintiff must supply evidence that all claim limitations are met). The survey never mentions the accused VCM Kit, meaning that survey respondents could have performed the surgery with CD Horizon Legacy or CD Horizon Solera implants using other instruments. Day 3 Tr. 643:17-24. Allowing the jury to hear evidence not tied to the claimed invention risks compensation for infringement that punishes beyond the reach of the statute. *See Fractus, S.A. v. Samsung*, 2011 WL 7563820, at *1 (E.D. Tex. Apr. 29, 2011); *see also* Dkt. 208, at 6 & n.8 (explaining that Medtronic’s SmartLink product can be used to perform the derotation step).¹ But pursuant to the final pretrial order, use of the VCM instruments is required for infringement. Specifically, the Joint Pre-Trial Order claims direct infringement of claims 4 and 5 of the ’358 patent based on surgeons’ use of “Medtronic CD Horizon Legacy Spinal System **with Vertebral Column Manipulation (‘VCM’)** Instrument Set and/or (2) Medtronic CD Horizon Solera Spinal System **with VCM Instrument Set.**” Dkt. 386 at 3 ¶ 1 (emphases added). That is, plaintiff’s allegation of infringement depends on surgeons using the VCM Instrument Set, as opposed to other instruments. Yet the survey does not provide evidence that surgeons use the VCM Instrument Set.

¹ The Court has excluded SmartLink products from this litigation. Dkt. 164.

Dr. Yassir also testified that a 2012 presentation by Dr. Lenke was evidence of direct infringement. Day 3 Tr. 831:24-832:17; PX 202. However, Dr. Yassir's testimony on this point was plainly deficient. For example, there is no evidence indicating when Dr. Lenke performed the surgeries in question, nor does the presentation actually demonstrate that Dr. Lenke directly infringed any asserted claim by doing so. Moreover, Dr. Yassir's testimony regarding alleged direct infringement depended on documents that either predate the issuance of Dr. Barry's patents or documents that involve undated surgeries. *See, e.g.*, Day 4 Tr. 895:19-23; 896:9-22; 996:25-997:5; 998:6-17; 999:1-9; 1004:10-23; PX 81; PX 109; PX 202. The problem is particularly acute for the '121 patent, which issued on January 29, 2013—Dr. Lenke's 2012 presentation cannot show direct infringement of a patent that had not yet issued.

Second, no reasonable factfinder could conclude that Medtronic induced infringement. Dr. Barry has failed to identify any actions by Medtronic sufficient to prove that it induced anyone to infringe. *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631-632 (Fed. Cir. 2015) (inducement requires “[e]vidence of active steps taken to encourage direct infringement” (quoting *Metro-Goldwyn-Mayer Studios Inc. v. Gorkster, Ltd.*, 545 U.S. 913, 936 (2005))). There is insufficient evidence that Medtronic itself actively encouraged infringement with knowledge of the patent and infringement; the scattered Medtronic materials that Dr. Barry relies upon are plainly insufficient, particularly for the '121 patent. *Id.*; *see also Mirror Worlds, LLC v. Apple Inc.*, 692 F.3d 1351, 1360 (Fed. Cir. 2012). Dr. Barry also contends that Dr. Lenke taught others to infringe, but Dr. Barry failed to demonstrate that Dr. Lenke's relevant actions were attributable to Medtronic. Day 4 Tr. 1029:22-1030:7. Nor is there any evidence of who Dr. Lenke allegedly taught, let alone that anyone taught by Dr. Lenke subsequently performed an infringing surgery. There is no showing of an alleged direct

infringement that occurred after a surgeon attended any of the trainings Dr. Barry alleges “actively encouraged infringement.” *Crystal Semiconductor Corp. v. TriTech Microelectronics Intern., Inc.*, 246 F.3d 1336, 1351 (Fed. Cir. 2001) (“Inducement only occurs if the party being induced directly infringes the patent.”).

Third, no reasonable factfinder could find that Medtronic has ever had the specific intent required for inducement—i.e., knowledge that the allegedly “induced acts constitute patent infringement.” *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1926 (2015); *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011). Merely learning about the patents and knowing how the products work does not show knowledge or willful blindness as to infringement, particularly given that Medtronic has substantial noninfringement arguments and that its products have many noninfringing uses. *See, e.g.*, Day 4 Tr. 991:12-20, 992:3-12.

Fourth, no reasonable factfinder could conclude that Medtronic knew of the patents-in-suit, let alone had knowledge that any claim was infringed, prior to at least February 2013. *Commil*, 135 S. Ct. at 1926.

II. No Reasonable Jury Could Find Inducement Under § 271(f)(1)

The evidence of inducement under § 271(f)(1) is plainly insufficient to support a finding of liability.

First, there is no evidence from which a reasonable jury could find that Medtronic shipped all or a substantial portion of the components of Dr. Barry’s alleged invention claimed in the ’121 patent from the United States to anyone abroad. *See* 35 U.S.C. § 271(f)(1). Dr. Barry’s witness conceded that he had “no evidence that Medtronic is shipping the VCM kit overseas.” Day 4 Tr. 1040:13-15. Further, the Neal survey was limited to domestic respondents. Day 3 Tr. 575:8-14. Finally, the 2009 email chain on which Dr. Barry relies predates the ’121 patent by

four years and cannot provide sufficient evidence of Medtronic's actions four years in the future. *See, e.g.*, Day 4 Tr. 1038:4-20; PX 622. Indeed, Dr. Barry's own witness agreed that a 2009 email "can't talk about what surgeons are doing in 2013." Day 4 Tr. 1038:18-20.

Second, there is no evidence from which a reasonable factfinder could conclude that Medtronic "actively induced" anyone abroad to assemble components shipped from the United States in a manner that would infringe a patent in suit if combined in the United States. *Id.* Dr. Barry has failed to marshal any evidence of actions by Medtronic that induced such a combination. Moreover, he has failed to show the specific intent required for active inducement—namely, that Medtronic had knowledge that third parties would practice the patent claims abroad. *Commil*, 135 S. Ct. at 1926-1928; *Promega Corp. v. Life Technologies Corp.*, 773 F.3d 1338, 1356 (Fed. Cir. 2014) (referring to "necessary knowledge and intent" to infringe under § 271(f)(1)). As with § 271(b), merely learning about the patents and knowing how the products work does not show knowledge or willful blindness as to infringement, particularly given that Medtronic has substantial noninfringement arguments and that its products have many noninfringing uses. *Commil*, 135 S. Ct. at 1926-1928.

Third, no reasonable factfinder could conclude that Medtronic knew of the patents-in-suit, let alone had knowledge that any claim was infringed until at least February 2013. *Id.*; *see also Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011).

III. No Reasonable Jury Could Find Willful Infringement

Dr. Barry has failed to marshal evidence that would allow a factfinder to find willful infringement by Medtronic. First, he has failed to prove direct infringement. Second, he has failed to prove active inducement under § 271(b) or § 271(f)(1). Third, Dr. Barry's patents are invalid. Fourth, even if Medtronic were found to induce infringement of a valid patent claim

under § 271(b) or § 271(f)(1), Dr. Barry has failed to establish that Medtronic did so in a subjectively willful manner. *See WesternGeco L.L.C. v. ION Geophysical Corp.*, ___ F.3d ___, 2016 WL 5112047, at *4-5 (Fed. Cir. Sept. 21, 2016); *see generally Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923 (2016). Dr. Barry has wholly failed to show that this is an “egregious case[] of misconduct beyond typical infringement.” *Halo*, 136 S. Ct. at 1935. In addition, Medtronic has demonstrated its good-faith belief that the patents-in-suit are invalid, *see infra* Pt. V, which remains a defense to allegations of willfulness.

IV. No Reasonable Jury Could Find Damages

Dr. Barry’s evidence of damages was insufficient on several grounds.

Medtronic renews its objection that Ms. Schenk’s testimony should have been excluded or stricken under *Daubert* for the reasons stated in its earlier briefing. Dkt. 209; Dkt. 254. But even if the testimony was admissible, it is still insufficient to support a damages verdict against Medtronic.

First, Ms. Schenk’s damages model was not limited to use of the accused VCM Kit to perform infringing procedures. Rather, the model includes procedures that are in no way linked to usage of Medtronic’s VCM Kit. For example, the CD Horizon Solera Spinal System works with Medtronic’s SmartLink derotators. Dkt. 208, at 6 & n.8.

Second, the damages model relies on wholly unreliable estimated data (actually estimates multiplied by estimates) to arrive at an estimated number of allegedly infringing procedures—including dubious and dated estimates of surgeries, Dr. Neal’s unreliable survey, and unfounded estimates of implants used per surgery. This amounts to unreasonable and unreliable speculation, particularly given that actual numbers—such as the number of times that a VCM kit

was opened—are available. *See ResQNet.com v. Lansa, Inc.*, 594 F.3d 860, 868-873 (Fed. Cir. 2010).

Third, the damages model simply assumes the existence of thousands of allegedly infringing surgeries abroad, without any evidence to support damages for overseas sales and infringement under § 271(f)(1).² To the extent that Ms. Schenk's analysis is based on Medtronic's purported shipment of rods outside the United States as a proxy for alleged infringement, it is again wholly unreliable and speculative. *See, e.g.*, Day 4 Tr. 1155:6-11. The analysis is in no way tied to shipment of the accused VCM Kits (or components thereof), assumes infringement with no support, and instead relies on shipment of a basic product (the rod) that has many uses in a variety of medical procedures.

Fourth, the damages model began measuring on the wrong date. Ms. Schenk's model began calculating damages on the date that the '358 patent issued in 2010, but Dr. Barry did not establish Medtronic's allegedly inducing acts, knowledge of the patent, and knowledge of infringement—if at all—until much later. *Commil*, 135 S. Ct. at 1926; *Global-Tech*, 563 at 766. Further, Dr. Neal's survey was limited in time to the period of February 2014 to February 2016—Dr. Barry could not be entitled to damages outside that time period, as Ms. Schenk opines.

Fifth, Ms. Schenk's model alleges an entirely implausible royalty of \$1200 per procedure for a non-exclusive license, Day 4 Tr. 1078:24-1079:3, despite the fact that Biomet pays Dr. Barry significantly less for an exclusive license and additional services. Further, Ms. Schenk provides no reasonable basis for the asserted revenue-per-surgery and price of pedicle screws in her analysis; her analysis simply utilizes Medtronic's gross profit margin, but makes no

² Medtronic cannot be held liable for activity abroad under § 271(b).

adjustment for even basic overhead—to say nothing of the cost of marketing and selling the allegedly infringing product.

V. The Evidence Compels Judgment of Invalidity

Medtronic contends that the evidence in Dr. Barry's own case compels a conclusion that the asserted claims of the '358 patent are invalid on multiple, independent grounds, either of which is individually sufficient to render the asserted claims invalid.³

First, claims 4 and 5 are invalid because Dr. Barry made a public use of the claims on multiple occasions in 2003, well before the critical date of December 30, 2003. Specifically, Dr. Barry himself admitted to at least three surgeries on August 4, August 5, and October 13—as well as numerous additional surgeries that used the claimed methods in 2002 and 2003. *See, e.g.*, Day 1 Tr. at 190:3-6; *id.* at 195:12-16; *id.* at 203:19-205:4. Mr. Pfefferkorn also admitted that Dr. Barry's modified instruments would have been publicly available in the hospital after surgeries. *See, e.g.*, Day 3 Tr. 692:14-25. Those surgeries constitute invalidating public uses under 35 U.S.C. § 102(b).

Second, claims 4 and 5 are invalid because Dr. Barry offered the claimed methods for sale on multiple occasions in 2003. Dr. Barry was paid his standard rate for the 2002 and 2003 surgeries during which he used the claimed methods. *See, e.g.*, Day 2 Tr. 430:11-12, 432:6-9. In addition, other members of the surgical team assisting with the surgeries, and the medical device manufacturers who supplied the tools and devices used in the surgeries, were compensated. *See, e.g.*, Day 2 Tr. 430:15-19; Day 3 Tr. 709:1-6; Day 3 Tr. 739:16-740:3. Dr. Barry and Mr.

³ Medtronic fully intends to supplement its contentions that both the '358 and '121 patent are invalid in its case-in-chief both for the grounds asserted here and for additional reasons set forth in prior pleadings and the pretrial order. Dkt. 386 at 6-7. However, because Dr. Barry's own testimony has proven the invalidity of his patents, Medtronic has included invalidity in this judgment as a matter of law.

Pfefferkorn also admitted that they met with representatives of DePuy Spine in July 2003 to discuss sale of Dr. Barry's claimed method. *See, e.g.*, Day 2 Tr. 435:23-436:1; Day 3 Tr. 671:10-14; Day 3 Tr. 674:20-675:4; Day 3 Tr. 677:10-15. These sales and offers establish that the claimed methods were on-sale before the December 30, 2003 critical date, rendering the claims invalid under § 102(b).

Dr. Barry did not marshal evidence sufficient to demonstrate that these public uses and sales were experimental. *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1186 (Fed. Cir. 1993); *Petrolite Corp. v. Baker Hughes Inc.*, 96 F.3d 1423, 1425 (Fed. Cir. 1996); *Sinskey v. Pharmacia Ophthalmics, Inc.*, 982 F.2d 494, 499 (Fed. Cir. 1992), *abrogated on other grounds by Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55 (1998).⁴ Accordingly, the claims are invalid.

Medtronic also contends that the evidence in Dr. Barry's own case compels a conclusion that the asserted claims of the '121 patent are invalid. Dr. Barry testified that he was unable to link derotator handles until he introduced slots into the design. *See, e.g.*, Day 1 Tr. 187:5-11; Day 2 Tr. 378:14-15; Day 1 Tr. 190:19-23. However, slots are never discussed in the specification of the patents-in-suit. The only place where the slots are even arguably shown in the '121 patent is in Figure 7, which was introduced into the specification in the continuation-in-part application filed August 10, 2005. Because the claims of the '121 patent require linking of the handles, and Dr. Barry has testified that linking of the handles can only be accomplished through the slots, the claims of the '121 patent are afforded the priority date of August 10, 2005 as the earliest filing date for the subject matter of the claims. *See Lockwood v. Am. Airlines, Inc.*,

⁴ While Medtronic maintains that Dr. Barry has failed to make out a case for experimental use based on the testimony in his case-in-chief, Medtronic also maintains its objection to the Court's exclusion of evidence relating to experimental use. Pursuant to the Court's instruction, Medtronic will separately proffer this evidence.

107 F.3d 1565, 1571 (Fed. Cir. 1997) (“Entitlement to a filing date does not extend to subject matter which is not disclosed.... [A] prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought.”). Thus, the critical date for purposes of § 102(b) for the ’121 patent is August 10, 2004. However, Dr. Barry testified that he discussed the cross-link publicly as early as February of 2004. *See, e.g.*, Day 1 Tr. 221:10-14; *see also* Day 2 Tr. 435:23-436:1; Day 3 Tr. 671:10-14; Day 3 Tr. 674:20-675:4; Day 3 Tr. 677:10-15. Further, the systems Dr. Barry constructed in surgeries prior to August 10, 2004 are invalidating prior systems—both because they were public uses *and* because they were sold and offered for sale. 35 U.S.C. § 102(b). Dr. Barry has not claimed any of the surgeries performed in 2004 were experimental, and in fact has claimed his invention was ready for patenting in January 2004. *See, e.g.*, Day 2 Tr. 8-10. Accordingly, the asserted claims of the ’121 patent are invalid.

VI. The Evidence Compels A Finding Of Laches

Again, Dr. Barry’s own testimony establishes that his ability to collect damages is limited under the equitable doctrines of laches. Dr. Barry’s deliberate delay in bringing suit against Medtronic was unreasonable and inexcusable and prejudiced Medtronic. *SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC*, 807 F.3d 1311, 1317 (Fed. Cir. 2015) (en banc), *cert. granted* 136 S. Ct. 1824 (2016).

VII. Dr. Barry Lacks Standing To Bring This Action

Trial testimony presented via Plaintiff’s own exhibits confirmed that Dr. Barry lacks standing to bring this action, substantially as alleged in Medtronic’s request that the Court dismiss the suit for lack of standing. *See* Dkt. 382; *see also, e.g.*, Day 2 Tr. 341:2-342:1; PX 261 (Biomet License Agreement); PX 267 (Biomet’s election not to pursue suit). Medtronic renews

its objection that Dr. Barry lacked standing to maintain this action at the time it was filed, and that the case should be dismissed.

CONCLUSION

For all the foregoing reasons, Medtronic respectfully requests that this Court enter judgment in favor of Medtronic under Federal Rule of Civil Procedure 50(a).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that all counsel of record who are deemed to have consented to electronic service are being served with a copy of this document via the Court's CM/ECF system per Local Rule CV-5(a) on November 10, 2016.

/s/ Julie P. Bookbinder

Julie P. Bookbinder